

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA

Plaintiff,

v.

WARNER-LAMBERT COMPANY LLC

Defendant.

Crim. No.

Violations:
Title 21, United States
Code Sections 331(a),
331(d), 352(f)(1),
and 355(a)

INFORMATION

**THE UNITED STATES ATTORNEY FOR THE DISTRICT OF MASSACHUSETTS
CHARGES THAT:**

GENERAL ALLEGATIONS

At all times material to this Information, unless otherwise alleged:

BACKGROUND

1. WARNER-LAMBERT COMPANY LLC (hereinafter "WARNER-LAMBERT"), was a corporation operating and existing under the laws of the State of Delaware. Its principal place of business was Morris Plains, New Jersey. WARNER-LAMBERT's Parke-Davis Division was engaged in, among other things, the development, manufacture, promotion, sale, and interstate distribution of prescription drugs intended for human use in the United States. WARNER-LAMBERT's pharmaceutical manufacturing facilities were located in Puerto Rico, from which it shipped products to all fifty states and the District of Columbia.

2. The Federal Food, Drug and Cosmetic Act ("FDCA"), among other things governs the lawful interstate distribution of drugs for human use. As codified at Title 21, United States Code, Sections 331 et seq., and specifically at § 355(b), the FDCA, and its implementing regulations, require that before a new drug may legally be distributed in interstate commerce, a sponsor of a new drug product must submit a New Drug Application ("NDA").

3. The FDCA required, at 21 U.S.C. § 355, that the NDA sponsor submit to the United States Food and Drug Administration ("FDA"), as part of an NDA, proposed labeling for the proposed intended uses for the drug which included, among other things, the conditions for therapeutic use. The NDA must also provide, to the satisfaction of FDA, data generated in

randomized and well-controlled clinical trials that demonstrates that the drug will be safe and effective when used in accordance with the proposed labeling.

4. The FDCA, at 21 U.S.C. § 355, prohibited the introduction into interstate commerce of any new drug, unless an approval of an NDA is effective. Only after the NDA, including the proposed labeling, was reviewed and approved by FDA, was the sponsor permitted by law to promote and market the drug, and only for the medical conditions of use specified in the approved labeling, for which use FDA had found sufficient evidence of safety and effectiveness. Uses unapproved by FDA, not included in the drug's approved labeling, are known as "unapproved uses" or "off-label uses."

5. The FDCA, and the regulations promulgated thereunder, required that in order to label or promote a drug for a use different than the conditions for use specified in the approved labeling, the sponsor had to file a new NDA, or amend the existing NDA, by, among other requirements, submitting the newly proposed indications for use and evidence, in the form of randomized and well-controlled clinical studies, sufficient to demonstrate that the drug would be safe and effective for the newly proposed therapeutic use or uses. Only upon approval of the new NDA could the sponsor promote the drug for the new intended use.

6. The FDCA, at 21 U.S.C. § 352(f)(1), provided that a drug was misbranded if, among other things, the labeling did not contain adequate directions for use. As the phrase is used in the FDCA, adequate directions for use cannot be written for medical indications or uses for which the drug had not been proven to be safe and effective through well-controlled clinical studies because that would be misleading under Section 352(a).

7. The FDCA, 21, U.S.C. §§ 331(a)(d), 333(a), and 355, prohibits the distribution in interstate commerce of an unapproved new drug or of a misbranded drug.

8. In or about 1993, WARNER-LAMBERT submitted an NDA for approval of a drug called Neurontin (also known by the chemical name gabapentin), which was a new drug within the meaning of 21 U.S.C. § 321(p) and 21 C.F.R. § 310.3 (h)(4) and (5). In that application, WARNER-LAMBERT sought to demonstrate the drug's safety and efficacy for, and sought approval for, use only as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy. On or about December 30, 1993, FDA approved Neurontin for that specific use only. This approved use for Neurontin will be referred to throughout this Information as the "Approved Use." Because WARNER-LAMBERT had not sought approval of any other uses nor submitted information in its NDA which demonstrated the safety and efficacy of Neurontin for any such uses, Neurontin was not approved for any use or condition other than the Approved Use. Further, Neurontin was not, pursuant to 21 U.S.C. § 355(i), exempt from the prohibition of introducing into interstate commerce a new drug for medical indications beyond the conditions prescribed, recommended, or suggested in the approved labeling thereof.

9. As described in this Information, from at least June of 1995 through at least August 20, 1996, unapproved uses for Neurontin included post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, bipolar disorder, alcohol withdrawal syndrome, amyotrophic lateral sclerosis (ALS), spinal cord injury, essential tremor, restless leg syndrome, reflex sympathetic dystrophy (RSD); and migraine headaches, among other uses.

These and other unapproved uses for Neurontin will be collectively referred to in this Information as the "Unapproved Uses."

10. WARNER-LAMBERT did not file a new NDA seeking FDA approval for any of these Unapproved Uses during the time period addressed in this Information. Of these Unapproved Uses, only post-herpetic neuralgia has ever received FDA approval, and that approval was applied for and received after the events described in this Information.

WARNER-LAMBERT'S STRATEGY FOR NEURONTIN

11. WARNER-LAMBERT conducted evaluations of the market potential for certain of the Unapproved Uses for Neurontin, including but not limited to: post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, and bipolar disorder.

12. In or about the fall of 1995, WARNER-LAMBERT's Southeast Customer Business Unit ("SECBU") created a planning document regarding Neurontin, which included a page titled: "SECBU RIGHT ON THE MARK WITH NEURONTIN AND PAIN" over a picture of a target and listed "Neurontin for Pain Strategies" including conference calls on pain and a pain consultant meeting.

13. Certain of WARNER-LAMBERT's annual strategic plans and other marketing planning documents for Neurontin included quarterly and annual goals, objectives, strategies, and tactics for increasing sales of the Unapproved Uses of the drug. The marketing plans budgeted for and funded these tactics.

14. From early 1995, on repeated occasions, WARNER-LAMBERT determined not to seek FDA approval for certain Unapproved Uses.

15. In or about April and May of 1995, WARNER-LAMBERT performed a Marketing Assessment of proposed psychiatric indications for Neurontin. In that Marketing Assessment, WARNER-LAMBERT forecast potential revenue from Neurontin for bipolar and anxiety treatment under two scenarios: with and without FDA approval. WARNER-LAMBERT's Neurontin Development Team and New Product Committee reviewed the potential psychiatric uses and concluded that the company would not seek approval to promote and sell the drug for these Unapproved Uses.

16. In or about July of 1995 WARNER-LAMBERT's assessment of Neurontin's market potential for neuropathic pain was distributed to its Neurontin Development Team and to a WARNER-LAMBERT Vice President for Marketing. That assessment stated that "there is no intention to fully develop the indication at this point." Full development would have required submission of an NDA to FDA for approval.

17. One of the principal factors WARNER-LAMBERT considered in determining whether to seek approval for Neurontin for other uses was the short patent protection available for Neurontin. Another factor was the negative impact such approval might generate on potential sales of another drug that WARNER-LAMBERT had been developing. The company expected this new drug would be approved by FDA not only for epilepsy but also for a variety of uses beyond Neurontin's Approved Use.

18. Once Neurontin's patent expired, other companies could seek approval to distribute generic equivalents of Neurontin. Such approval, however, would be limited to the approved therapeutic use for Neurontin set forth in WARNER-LAMBERT's original NDA approval for Neurontin. If WARNER-LAMBERT sought and obtained approval for any of the

Unapproved Uses, then upon expiration of the patent, generic equivalents of Neurontin could also be sold for those Unapproved Uses. WARNER-LAMBERT was concerned that under those circumstances the generic equivalents would undermine sales of the new drug that was under development.

WARNER-LAMBERT'S PROMOTION OF NEURONTIN FOR UNAPPROVED USES

19. From in or about June of 1995 through in or about August 20, 1996, by certain of the conduct described in greater detail below, WARNER-LAMBERT promoted the sale and use of Neurontin for certain conditions other than the Approved Use in Massachusetts and elsewhere:

OFF-LABEL PROMOTION THROUGH SALES REPRESENTATIVES

20. In October 1995, a member of WARNER-LAMBERT's Epilepsy Disease Team circulated a memorandum to a group including other senior members of WARNER-LAMBERT's Epilepsy Disease Team noting that data purchased from an outside vendor showed that doctors had reported that the main message of certain sales pitches (known as "details"), given by 10 of 50 WARNER-LAMBERT sales representatives for whom data was available in a two month period, was for off-label use of Neurontin. Nine were for pain and one was for reflex sympathetic dystrophy, a painful nerve damage syndrome.

21. On or about July 10, 1996, a WARNER-LAMBERT sales representative met with a doctor in Monroe, Louisiana, and detailed a doctor on Neurontin for the treatment of pain.

22. Also in 1996, a sales representative created a document that stated that sales representatives could ask doctors during a Neurontin detail if they ever used other anti-epileptic drugs for painful neuropathies and could mention that approximately 35% of all Neurontin use is non-seizure. This same document, entitled "Neurontin Can Do/Can't Do," stated that sales

representatives could do lunch programs on Neurontin and pain. The document indicated that it was to be forwarded to the Northcentral Customer Business Unit.

OFF-LABEL PROMOTION THROUGH MEDICAL LIAISONS

23. WARNER-LAMBERT employed "medical liaisons" who were presented to physicians as employees of the company's Medical and Scientific Affairs Department. On the following occasion, a WARNER-LAMBERT medical liaison promoted Neurontin for Unapproved Uses:

(a) In or about June of 1996, a WARNER-LAMBERT sales representative requested that a WARNER-LAMBERT medical liaison make a presentation at Longwood Gardens in Kennett Square, Pennsylvania, to a group of physicians who were members of a local medical society.

(b) The sales representative and the medical liaison selected the topic for the presentation to the local medical society. After deciding in consultation with the sales representative that Neurontin would be the topic of the presentation, the medical liaison prepared the presentation.

(c) Among the topics of the presentation was the use of Neurontin for Unapproved Uses.

(d) During the presentation, in the presence of the sales representative, the medical liaison promoted the use of Neurontin in the treatment of a number of Unapproved Uses.

(e) After the presentation, a WARNER-LAMBERT Medical Director praised the event as "another great example of use of the medical liaisons" and an Area Business Manager called it an "outstanding utilization of . . . one of the medical affairs liaisons."

24. In or about May 1996, a WARNER-LAMBERT Medical Director based in the Northeast CBU sent a voicemail message to the Medical Liaisons in the Northeast CBU in which he stated:

What we'd like you to do is, any time you're called out just make sure that your main focus out of what you're doing is on Neurontin . . . When we get out there, we want to kick some ass, we want to sell Neurontin on pain. All right? And monotherapy and everything that we can talk about, that's what we want to do.

One or more Medical Liaisons in the Northeast CBU interpreted this statement to mean that he or she should promote Neurontin for Unapproved Uses and thereafter, in or about May and June 1996, promoted Neurontin for neuropathic pain, an unapproved use.

OFF-LABEL PROMOTION THROUGH CONSULTANTS' MEETINGS
AND ADVISORY BOARDS

25. WARNER-LAMBERT organized a consultant meeting at the Jupiter Beach Resort in Palm Beach, Florida on April 19-21, 1996. Approximately 42 physicians attended the meeting, including nine physicians who made presentations relating to Unapproved Uses of Neurontin.

26. WARNER-LAMBERT invited certain doctors to this meeting based upon their history of writing a large number of prescriptions for Neurontin or similar drugs. As part of this event, WARNER-LAMBERT paid for accommodations and meals for the invited doctors and

their spouse or guest, and paid an honorarium to each of the doctor attendees. Doctors who acted as faculty were paid between \$1,500 and \$2,000.

27. Among the presentations made to the physicians in attendance was one relating to Unapproved Uses entitled "Reduction of Pain Symptoms During Treatment with Gabapentin." In the meeting's agenda, this presentation was listed as "Anticonvulsant Advances." During this presentation, Neurontin was promoted for use in the treatment of pain.

28. Another presentation made at the Jupiter Beach conference was entitled "Anticonvulsant Advances: Nonepileptic Uses of Anti Epileptic Drugs." During this presentation, Neurontin was promoted for use in the treatment of essential tremor, episodic dyscontrol, and pain.

29. On or about May 8, 1996, following the Jupiter Beach conference, WARNER-LAMBERT circulated to employees in the Northeast region the agenda to the meeting, specifying the off-label topics, the faculty list, the attendee list and presentation abstracts discussing the off-label content of the presentations. WARNER-LAMBERT told its employees that: "[t]he meeting was a great success and the participants were delivered a hard-hitting message about Neurontin." WARNER-LAMBERT distributed to these employees a form entitled "Jupiter Beach Trending Worksheet" which was intended to be used to gauge the effect of the meeting on the prescribing by doctors who attended the Jupiter Beach meeting.

30. From August 1-5, 1996, WARNER-LAMBERT organized an "advisory board meeting," in Atlanta, Georgia in conjunction with the 1996 Summer Olympics. WARNER-LAMBERT expressly instructed several of the physician speakers to address some of the Unapproved Uses.

31. During that meeting, WARNER-LAMBERT hosted doctors at the Chateau Elan Winery and Resort, in Atlanta, Georgia, and paid all the expenses for eighteen "consultants" and their spouses to attend the Olympics, including tickets to the closing ceremonies. The company had already had numerous opportunities to consult with the doctors and, in fact, many of them had spoken on WARNER-LAMBERT's behalf at prior meetings.

32. Certain of the physician speakers promoted Neurontin for unapproved uses in their presentations.

OFF-LABEL PROMOTION THROUGH TELECONFERENCES

33. In or about January, 1996, a WARNER-LAMBERT Vice President of the Southeast Customer Business Unit sent a memorandum to WARNER-LAMBERT sales representatives listing certain goals, including: "Utilize the Medical Liaison Group to target the Neurontin, Pain & Psychiatric market. Objective to conduct twice weekly Pain Teleconferences moderated by key Neuro Consultants. Goals 250 Physicians Participants quarterly."

34. On or about March 1, 1996, WARNER-LAMBERT sponsored such a teleconference moderated by a WARNER-LAMBERT employee with a pain specialist as a speaker on Neurontin. The speaker promoted Neurontin for the treatment of pain to doctors participating in the teleconference.

35. On or about March 28, 1996, a WARNER-LAMBERT Medical Director in the Northcentral Customer Business Unit sent a memorandum to WARNER-LAMBERT Medical Liaisons in that unit instructing them to hold a series of teleconferences with doctors to provide clinical updates on Neurontin, including monotherapy epilepsy data and non-epilepsy use data entitled "Neurontin, A Clinical Update."

36. In or about May, 1996, a WARNER-LAMBERT Medical Director held such a teleconference entitled "Neurontin, A Clinical Update" in which the Medical Director promoted off-label uses of Neurontin to the doctors participating in the teleconference.

COUNT ONE: 21 U.S.C. §§ 331(d), 333(a)(2) & 355(a)

(Distribution of an Unapproved New Drug)

37. The allegations contained in paragraphs 1 through 36 are realleged and incorporated herein as if set forth in full.

38. Beginning as early as in or about April 1995, and continuing thereafter until at least in or about August 20, 1996, in the District of Massachusetts, and elsewhere,

WARNER-LAMBERT,

after previously having been convicted of violating the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 333, did introduce and cause the introduction into interstate commerce from Puerto Rico and elsewhere, directly and indirectly, into Massachusetts and elsewhere, quantities of Neurontin, a drug within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(p), which drug was intended for use for the treatment of neuropathic pain, bipolar disorder, as monotherapy for epilepsy, and other Unapproved Uses. No approval, pursuant to 21 U.S.C. § 355, was in effect with respect to Neurontin for use in these conditions.

All in violation of 21 U.S.C. §§ 331(d), 333(a)(2), and 355(a).

COUNT TWO: 21 U.S.C. §§ 331(a), 333(a)(2) & 352(f)(1)

(Distribution of a Misbranded Drug: Inadequate Directions for Use)



39. The allegations contained in paragraphs 1 through 36 are realleged and incorporated herein as if set forth in full.

40. Beginning as early as April 1995, and continuing thereafter until at least in or about August 20, 1996, in the District of Massachusetts and elsewhere,

WARNER-LAMBERT,

after previously having been convicted of violating the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 333, did introduce and cause the introduction into interstate commerce from Puerto Rico and elsewhere, directly and indirectly, into Massachusetts and elsewhere, quantities of Neurontin, a drug within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(p), which drug was intended for use for the treatment of neuropathic pain, bipolar disorder, as monotherapy for epilepsy, and other Unapproved Uses, and which was misbranded within the meaning of 21 U.S.C. § 352(a), in that Neurontin's labeling lacked adequate directions for such uses.

All in violation of 21 U.S.C. §§ 331(a), 333(a)(2), and 352(f)(1).


MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS
THOMAS E. KANWIT
ASSISTANT U.S. ATTORNEY

May 13, 2004



U.S. Department of Justice

*Michael J. Sullivan
United States Attorney
District of Massachusetts*

Main Reception: (617) 748-3100

*John Joseph Moakley United States Courthouse
Suite 9200
1 Courthouse Way
Boston, Massachusetts 02210*

May 13, 2004

Robert B. Fiske, Jr., Esq.
James P. Rouhandeh, Esq.
Davis Polk & Wardwell
450 Lexington Avenue
New York, NY 10017

Re: Warner-Lambert Company LLC

Dear Messrs. Fiske and Rouhandeh:

This letter sets forth the Agreement between the United States Attorney for the District of Massachusetts ("the U.S. Attorney") and your client, Warner-Lambert Company LLC, a Delaware company ("Warner-Lambert")(collectively, "the Parties"), in the above-captioned case. The Agreement is as follows:

1. Change of Plea

On or before May 13, 2004, or such other date as the Court may set, Warner-Lambert shall waive indictment and plead guilty to all counts in the Information, a copy of which is attached hereto as Exhibit A, which Information charges Warner-Lambert with violations of Title 21 United States Code Sections 331(a), 331(d), 333(a), 352(f)(1) and 355. Warner-Lambert expressly waives any statute of limitations defense that it may have in connection with these crimes. Warner-Lambert expressly and unequivocally admits that it committed the crimes charged in the Information. Warner-Lambert agrees that the facts set forth in the Information are true.

2. Sentencing Guidelines

The United States and Warner-Lambert agree that the following provisions of the United States Sentencing Guidelines ("U.S.S.G.") will govern sentencing of Warner-Lambert with respect to the Information:

- (a) as indicated at the end of this section on the Sentencing Guidelines, pursuant to U.S.S.G. § 8C2.4(a)(2) and 18 U.S.C. § 3571(d) the parties agree that the pecuniary gain to Warner-Lambert derived from this offense for criminal sentencing purposes is \$150,000,000;
- (b) pursuant to U.S.S.G. § 8C2.6, the parties agree that the appropriate multiplier to be applied as to Warner-Lambert is 1.6, reaching that figure through the following means:
 - i. pursuant to U.S.S.G. § 8C2.5, the culpability score is calculated as follows:
 - (A) the parties agree that the base score is 5 pursuant to § 8C2.5(a);
 - (B) the parties agree that 2 points should be deducted pursuant to § 8C2.5(g)(2); and
 - (C) the United States contends that 5 points should be added pursuant to U.S.S.G. § 8C2.5(b)(1)(A)(i) and/or (ii); but Warner-Lambert contends that 3 points should be added pursuant to § 8C2.5(b)(3)(B)(i).
 - ii. pursuant to § 8C2.6, the applicable range for a multiplier is 1.6 to 3.2 according to the United States and 1.2 to 2.4 according to Warner-Lambert. The parties agree that the appropriate multiplier to be applied as to Warner-Lambert is 1.6.
- (c) the Parties agree that there is no basis for a departure under the Sentencing Guidelines, either upward or downward.

The United States represents and for purposes of this Plea Agreement, Warner-Lambert does not object that, pursuant to U.S.S.G. § 8C2.4(a) and 18 U.S.C. § 3571(d), the gain to Warner-Lambert from this offense for criminal sentencing purposes is \$150,000,000. Warner-Lambert and the United States both acknowledge that the gain figure cannot be determined with precision and that the gain figure of \$150,000,000 for criminal sentencing purposes is an estimate. The United States and Warner-Lambert further agree that calculation of the criminal fine under U.S.S.G. § 8C2.4(a)(2) is appropriate under the circumstances of this case.

3. Agreed Disposition

The United States and Warner-Lambert agree pursuant to Fed. R. Crim. P. 11(c)(1)(C) that the following sentence is the appropriate disposition of the Information:

- (a) a criminal fine in the amount of two hundred forty million dollars, (\$240,000,000), to be paid within fourteen days of sentencing; and
- (b) a mandatory special assessment of \$800 pursuant to 18 U.S.C. § 3013, which shall be paid to the Clerk of Court on or before the date of sentencing.

In light of the pending civil action, United States ex rel. David Franklin v. Parke-Davis Division of Warner-Lambert and Pfizer Inc., Civil Action No. 96-11651-PBS (D. Mass.), and the Civil Settlement Agreement between Warner-Lambert and others and the United States relating to the civil action which is being signed contemporaneous with this Plea Agreement (the "Civil Settlement Agreement," a copy of which is attached hereto as Exhibit B), the parties agree that the appropriate disposition of this case does not include a restitution order because the losses suffered here, if any, will be recompensed fully from amounts paid as part of the Civil Settlement Agreement; and because the process of fashioning a restitution order would unduly complicate and prolong the sentencing process. See 18 U.S.C. § 3663(a)(1)(B)(ii). Therefore, the United States agrees that it will not seek a separate restitution order as to Warner-Lambert as part of the resolution of the Information and the Parties agree that the appropriate disposition of this case does not include a restitution order.

4. No Further Prosecution of Warner-Lambert

Except as set forth below and other than as set forth in the Information, a copy of which is attached hereto as Exhibit A, the United States agrees that it shall not further prosecute Warner-Lambert or Pfizer Inc for: (i) any conduct within the scope of the grand jury investigation by the United States Attorney for the District of Massachusetts related to Warner-Lambert's product Neurontin; and (ii) any conduct related to Neurontin which is presently known to the United States Attorney for the District of Massachusetts.

The United States does not decline criminal prosecution of Warner-Lambert, Pfizer Inc, Pharmacia, or any related entity for conduct relating to products other than Neurontin.

The U.S. Attorney expressly reserves the right to prosecute any individual, including but not limited to present and former officers, directors, employees and agents of Warner-Lambert, in connection with the conduct encompassed by this Plea Agreement or within the scope of the grand jury investigation.

This declination is contingent upon: (1) the guilty plea of Warner-Lambert to the Information, attached hereto as Exhibit A, being accepted by the Court and not withdrawn; (2) Warner-Lambert entering into, simultaneously with this agreement, and completing its obligations under, the Civil Settlement Agreement between Warner-Lambert and the United States, Exhibit B hereto; and (3) the completion of Warner-Lambert's obligations under this Agreement.

5. Corporate Integrity Agreement

Contemporaneous with the execution of this agreement, Warner-Lambert shall enter into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("Inspector General") for the United States Department of Health and Human Services. A breach of the Corporate Integrity Agreement, incorporated by reference in the Civil Settlement Agreement, does not constitute a breach of this Plea Agreement, and any disputes arising under the CIA shall be resolved exclusively through the dispute resolution provisions of the CIA.

6. Sentencing

Warner-Lambert acknowledges that it has been previously convicted under Title 21 United States Code section 333. As a result of this prior conviction, Warner-Lambert acknowledges and agrees that, pursuant to Title 21 United States Code Section 333(a)(2), Warner-Lambert is pleading to charges which constitute felony offenses.

The U.S. Attorney specifically may, at his sole option, be released from his commitments under this Agreement, including, but not limited to, his agreement that paragraph 4 constitutes the appropriate disposition of this case, if at any time between his execution of this Agreement and sentencing, Warner-Lambert:

- (a) Fails to admit a complete factual basis for the plea;
- (b) Fails to truthfully admit its conduct in the offenses of conviction;
- (c) Falsely denies, or frivolously contests, relevant conduct for which Warner-Lambert is accountable under U.S.S.G. § 1B1.3;
- (d) Gives false or misleading testimony in any proceeding relating to the criminal conduct charged in this case and any relevant conduct for which Warner-Lambert is accountable under U.S.S.G. § 1B1.3; or
- (e) Engages in acts which form a basis for finding that Warner-Lambert has obstructed or impeded the administration of justice under U.S.S.G. § 3C1.1.

Warner-Lambert expressly understands that it may not withdraw its plea of guilty, unless the Court rejects this Agreement under Fed. R. Crim. P. 11(c)(5). If the sentencing judge rejects this Agreement, this Agreement shall be null and void at the option of either the United States or Warner-Lambert. In this regard, Warner-Lambert hereby waives any defense to any charges which it might otherwise have under the Speedy Trial Act and tolls any applicable statute of limitations until 60 days after this Agreement is no longer in full force and effect.

7. Payment of Mandatory Special Assessment

Warner-Lambert agrees to pay the mandatory special assessment to the Clerk of the Court on or before the date of sentencing.

8. Cooperation

Warner-Lambert agrees to cooperate completely and truthfully with the U.S. Attorney in connection with his on-going investigation and prosecution of others for alleged violations of federal criminal law arising out of his investigation. Warner-Lambert understands and agrees that such cooperation shall include the following, if requested by the U.S. Attorney:

- (a) prompt production to the U.S. Attorney of any document or record in the possession, custody or control of Warner-Lambert relating to the subject matter of the investigation;
- (b) taking all reasonable measures available to Warner-Lambert to ensure that present and former officers, directors, agents and employees of Warner-Lambert cooperate truthfully and completely with the U.S. Attorney in connection with his on-going investigation and prosecutions; and
- (c) taking all reasonable measures available to Warner-Lambert to make all present and former officers and employees of Warner-Lambert or Pfizer Inc available for interviews by federal law enforcement personnel, upon reasonable notice.

Provided, however, notwithstanding any provision of this agreement, that: (1) Warner-Lambert is not required to request of its present or former officers, directors, employees or agents that they forego seeking the advice of an attorney nor that they act contrary to that advice; (2) Warner-Lambert is not required to take any action against their officers, directors, employees, or agents for following their attorney's advice; and (3) Warner-Lambert is not required to waive any privilege or claim of work product.

9. Probation Department Not Bound By Agreement

The sentencing disposition agreed upon by the parties and their respective calculations under the Sentencing Guidelines are not binding upon the United States Probation Office.

Warner-Lambert and the United States Attorney's Office agree to seek a sentencing by the District Court immediately following the Rule 11 plea hearing and do not object to the Court proceeding to sentence Warner-Lambert in the absence of a Presentence Report in this case. Warner-Lambert understands that the decision whether to proceed immediately following the plea hearing with the sentencing proceeding, and to do so without a Presentence Report, is exclusively that of the United States District Court.

10. Civil Liability

Warner-Lambert's alleged civil liability to the United States in connection with the matters under investigation by the United States, as set forth in paragraph 4 of this agreement, is resolved as set forth in the Civil Settlement Agreement, attached hereto as Exhibit B, according to the terms set forth in that agreement.

11. Breach of Agreement

If the U.S. Attorney for the District of Massachusetts determines that Warner-Lambert has failed to comply with any material provision of this Agreement, the United States may, at its sole option, be released from its commitments under this Agreement in their entirety by notifying Warner-Lambert, through counsel or otherwise, in writing. The United States may also pursue all remedies available to it under the law, irrespective of whether it elects to be released from its commitments under this Agreement. Warner-Lambert recognizes that no such breach by it of an obligation under this Agreement shall give rise to grounds for withdrawal of its guilty plea. Warner-Lambert understands that, should it breach any material provision of this agreement, the U.S. Attorney will have the right to use against Warner-Lambert before any grand jury, at any trial or hearing, or for sentencing purposes, any statements which may be made by it and any information, materials, documents or objects which may be provided by it to the government subsequent to this Agreement, without any limitation.

Warner-Lambert understands and agrees that this 11(c)(1)(C) plea agreement and its agreed upon criminal disposition:

- (1) are wholly dependent upon Warner-Lambert's entering into, simultaneously with this agreement, and completing its obligations under, the attached Civil Settlement Agreement, including the requirement in that agreement that Warner-Lambert pay to the United States and to Medicaid Participating States and Consumer Participating States the amount of one hundred ninety million dollars (\$190,000,000) in accordance with the terms of the Civil Settlement Agreement; and that
- (2) failure by Warner-Lambert to comply with the material terms of either this agreement or the attached Civil Settlement Agreement will constitute a breach of this plea agreement.

In the event that Warner-Lambert at any time hereafter breaches any material provision of this plea agreement, Warner-Lambert understands that (1) the United States will as of the date of that breach be relieved of any obligations it may have in this agreement and the attached Civil Settlement Agreement, including but not limited to the promise not to further prosecute Warner-Lambert, as set forth in paragraph 4 of this plea agreement; and (2) Warner-Lambert will not be relieved of its obligations to make the payments set forth in this plea agreement and in the attached Civil Settlement Agreement, nor will it be entitled to any return of any monies already paid. Nothing in

this Agreement would preclude Warner-Lambert from contesting whether a breach had occurred if a subsequent Indictment were brought.

12. Corporate Authorization

Warner-Lambert shall provide to the U.S. Attorney and the Court a certified copy of a resolution of the Board of Directors of Warner-Lambert, affirming that the Board of Directors of Warner-Lambert has authority to enter into the Plea Agreement and has (1) reviewed the Information in this case and the proposed Plea Agreement; (2) consulted with legal counsel in connection with the matter; (3) voted to enter into the proposed Plea Agreement; (4) voted to authorize Warner-Lambert to plead guilty to the charges specified in the Plea Agreement; and (5) voted to authorize the individual identified below to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement.

Warner-Lambert agrees that a duly authorized corporate officer or member of the board of directors will appear on behalf of Warner-Lambert and will enter the guilty plea and will also appear for the imposition of sentence.

13. Who is Bound by Agreement

This Agreement is binding upon the Attorney General of the United States, the Department of Justice, and all United States Attorneys on the matters as set forth in paragraph 4 but cannot and does not bind the Tax Division of the U.S. Department of Justice or the Internal Revenue Service of the U.S. Department of the Treasury. Warner-Lambert also understands that this agreement does not bind any state or local prosecutive authorities.

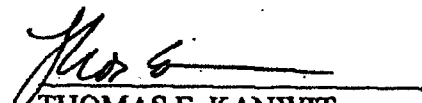
14. Complete Agreement

This letter, together with the attached Information, Civil Settlement Agreement and the United States Attorney's Side Letter to Warner-Lambert of May 12, 2004, set forth the complete and only agreement between the parties relating to the disposition of this case. No promises, representations or agreements have been made other than those set forth in this letter, and the three attached and referenced documents. This Agreement supersedes prior understandings, if any, of the parties, whether written or oral, with the exception of those promises and representations set forth in the attached documents. This Agreement can be modified or supplemented only in a written memorandum signed by the parties or on the record in court.

If this letter accurately reflects the Agreement between the U.S. Attorney and Warner-Lambert, please have Warner-Lambert sign the Acknowledgment of Agreement below. Please also sign below as Witness. Return the original of this letter to Assistant U.S. Attorney Thomas E. Kanwit of the District of Massachusetts.

Very truly yours,

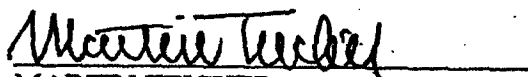

MICHAEL J. SULLIVAN
United States Attorney


THOMAS E. KANWIT
Assistant U.S. Attorney

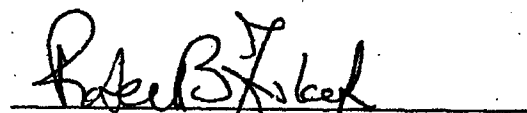
Corporate Acknowledgment of Plea Agreement

The Board of Directors has authorized me to execute this Plea Agreement and the attached Civil Settlement Agreement on behalf of Warner-Lambert Company. The Board has been well informed regarding these documents in their entirety and has discussed them fully with Warner-Lambert's attorneys. The Board acknowledges that these documents fully set forth Warner-Lambert's agreements with the United States. The Board further states that no additional promises or representations have been made to the Board by any officials of the United States in connection with this matter, other than those set forth in this plea agreement and in the attached Civil Settlement Agreement.

Dated: 5/11/04


MARTIN TEICHER
Vice President
Warner-Lambert Company LLC

Dated: 5/11/04


ROBERT B. FISKE, JR. ESQUIRE
Davis Polk & Wardwell

Dated: 5/11/04


JAMES P. ROUHANDEH, ESQUIRE
Davis Polk & Wardwell